157 B

31

No. 06-179

IN THE

Supreme Court of the United States

DONNA RIEGEL, individually and as administrator of the ESTATE OF CHARLES R. RIEGEL,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

Daniel J. Popeo
Richard A. Samp
(Counsel of Record)
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

Date: October 19, 2007

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTION PRESENTED

Whether the Medical Device Amendments to the federal Food, Drug, and Cosmetic Act preempt state-law products liability claims challenging the design, manufacturing, and labeling of medical devices that the Food and Drug Administration has found to be safe and effective pursuant to its rigorous Premarket Approval process.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iv

INTERESTS OF THE *AMICI CURIAE* 1

STATEMENT OF THE CASE 2

SUMMARY OF ARGUMENT 6

ARGUMENT 9

I. PETITIONERS' DESIGN DEFECT AND FAILURE-TO-WARN CLAIMS ARE PREEMPTED BY § 360k(a) 9

A. The Language of § 360k(a) Has Been Interpreted in Lohr and Other Cases As Evidence of a Congressional Intent to Preempt Common Law Causes of Action 10

B. Section § 360k(a) Does Not Exclude State Rules of General Applicability from Being Classified as "Requirement[s]" 13

C. States Undermine the Objectives of the MDA When They Second-Guess an FDA Decision to Approve Marketing of Life-Saving Medical Devices Pursuant to FDA-Mandated Design and Labeling Requirements 14

II. PETITIONERS' DESIGN DEFECT AND FAILURE-TO-WARN CLAIMS ARE IMPLIEDLY PREEMPTED BY THE MDA 15

Page

A. Implied Preemption Is Fairly Encompassed Within the Question Presented 16

B. The Court Has Regularly Inferred Congressional Intent to Preempt State Laws That Conflict with Federal Law 17

C. Recovery Under the Riegels' Causes of Action Is Preempted Because It Would Undermine the PMA Process Established by Congress 18

D. The Existence of an Express Preemption Provision in the MDA Does Not Preclude an Implied Preemption Finding 23

CONCLUSION 24

TABLE OF AUTHORITIES

Page(s)

Cases:

Barnett Bank of Marion County, N.A. v. Nelson,
517 U.S. 25 (1996) 17
Bates v. Dow AgroSciences LLC,
544 U.S. 431 (2005) 7, 11, 12
Buckman v. Plaintiffs' Legal Comm.,
531 U.S. 341 (2001) ..... *passim*
Cipollone v. Liggett Group, Inc.,
505 U.S. 504 (1992) 7, 11
Florida Lime and Avocado Growers, Inc. v. Paul,
373 U.S. 132 (1963) 18
Freightliner Corp. v. Myrick,
514 U.S. 280 (1995) 17
Geier v. American Honda Motor Co.,
529 U.S. 861 (2000) 19, 23
Hines v. Davidowitz,
312 U.S. 52 (1941) 2, 18
Jones v. Rath Packing Co.,
430 U.S. 519 (1977) 17
Lebron v. Nat'l Railroad Passenger Corp.,
513 U.S. 374 (1995) 16
Medtronic, Inc. v. Lohr,
518 U.S. 470 (1996) ..... *passim*
Rice v. Santa Fe Elevator Corp.,
331 U.S. 218, 230 (1947) 17
Wisconsin Public Intervenor v. Mortier,
501 U.S. 597 (1991) 17, 18
Yee v. Escondido,
503 U.S. 519 (1992) 16

Page(s)

Statutory and Regulatory Provisions:

Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.* 8

Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (1976)(chiefly codified at 21 U.S.C. § 360c *et seq.*) ..... *passim*

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 11, 12
7 U.S.C. § 136y(b) 11

National Traffic and Motor Safety Act of 1966, 15 U.S.C. § 1381 *et seq.* 20, 23

21 U.S.C. § 360e(e) 14
21 U.S.C. § 360h(e) 14
21 U.S.C. § 360k(a) ..... *passim*
21 U.S.C. § 360k(a)(1) 4

21 C.F.R. § 814.20 19
21 C.F.R. § 814.44 19
21 C.F.R. § 814.80 19

Page(s)

Miscellaneous:

FDA, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) 21

Public Health Advisory, FDA, Worsening Depression and Suicidality in Patients Being Treated With Antidepressant (Mar. 22, 2004), *available at* http://www.fda.gov/cder/drug/antidepressants/AntidepressanstPHA.htm. 22

Robert D. Gibbons, Ph.D. et al., *Early Evidence on the Effects of Regulators' Suicidality Warnings on SSRI Prescriptions and Suicide in Children and Adolescents*, 164 Am. J. Psychiatry 1356, 1358-1359 (2007) 22

Anne M. Libby, Ph.D. et al., *Decline in Treatment of Pediatric Depression After FDA Advisory on Risk of Suicidality With SSRIs*, 164 Am. J. Psychiatry 884, 887 (2007) 22

H.R. Rep. No. 853, 94th Cong., 2d Sess. 9 (1976), *reprinted in* Daniel F. O'Keefe, Jr. & Robert A. Spiegel, *An Analytical Legislative History of the Medical Device Amendments of 1976*, App. III (1976) 15

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government. To that end, WLF has frequently appeared as *amicus curiae* in this and other federal courts in cases involving preemption issues, to point out the economic inefficiencies often created when multiple layers of government seek simultaneously to regulate the same business activity. *See, e.g., Bates v. Dow AgroSciences LLC,* 544 U.S. 431 (2005); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000); *United States v. Locke,* 529 U.S. 89 (2000).

WLF is particularly concerned that individual freedom and the American economy both suffer when state law, including state tort law, imposes upon industry an unnecessary layer of regulation that frustrates the objectives or operation of specific federal regulatory regimes, such as (in this case) the Medical Device Amendments (MDA).

At issue here is whether Congress intended to preempt Petitioners' causes of action. WLF agrees with Respondents and the U.S. Court of Appeals for the Second Circuit that Congress's preemptive intent under the facts of this case is manifested by the MDA's express preemption provision, 21

---

[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

U.S.C. § 360k(a). Quite apart from that provision, however, WLF submits that the MDA impliedly preempts Petitioner's causes of action, because the common law rules Petitioner espouses "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

WLF has no direct interest, financial or otherwise, in the outcome of this case. It is filing due solely to its interest in the important preemption issues raised by this case. WLF is filing this brief with the consent of both parties, who have filed blanket letters of consent with the Clerk of the Court.

STATEMENT OF THE CASE

This case involves a state-law personal injury suit filed by Charles Riegel, a New York resident who claimed to have suffered injury during heart surgery involving use of the Evergreen Balloon Catheter, a medical device that was manufactured by Respondent Medtronic, Inc. and entered the market pursuant to the Food and Drug Administration's (FDA) rigorous premarket approval (PMA) process.[2] The suit alleged five common law causes of action: (1) negligence in the design, testing, inspection, manufacture, distribution, labeling, marketing, and sale of the Evergreen Balloon Catheter; (2) strict liability in tort; (3) breach of express warranty; (4) breach of implied warranty; and (5) loss of consortium. Pet. App. 4a-5a.

At issue here is whether federal law preempts certain of those causes of action. The district court held that several of

---

[2] His wife, Donna Riegel, also sued for loss of consortium. Following his death, the Court granted Donna's motion to be substituted for Charles (in her capacity as administrator of the estate) as a party to these proceedings.

the causes of action – those involving strict liability, breach of implied warranty, and all of the negligence claims except for the negligent manufacturing claim – were preempted by the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (1976) (chiefly codified at 21 U.S.C. § 360c *et seq.*). The district court based its preemption finding on the MDA's express preemption provision, 21 U.S.C. § 360k(a). Pet. App. 5a. Following discovery, the district court granted summary judgment to Medtronic on the remaining claims. *Id.* It dismissed the express warranty claim because Medtronic had clearly disclaimed any express warranty, and it dismissed the negligent manufacturing claim on the grounds that there was insufficient evidence that the Evergreen Balloon Catheter had burst because of negligent manufacture. *Id.*

The Second Circuit affirmed. *Id.* at 1a-54a. The court based much of its legal analysis on this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), which held that § 360k(a) does not preempt state law tort claims filed against manufacturers of Class III medical devices that reach the market by means of the § 510(k) process.[3] The appeals court noted that while devices that can meet the § 510(k) eligibility criteria can gain market access after minimal FDA review, the PMA review process (required for all Class III devices – such as the Evergreen Balloon Catheter – that do not qualify for § 510(k) process) is far more "lengthy and rigorous." Pet. App. 8a. The court also noted that only about 1% of new

---

[3] The "§ 510(k) process" (also known as the "premarket notification" process) is the name generally given to the process that allows medical devices to reach the market based on a showing that they are "substantially equivalent" to medical devices that were already being marketed at the time of the MDA's adoption in 1976. *Lohr*, 518 U.S. at 478. The MDA also included a "grandfathering" provision that allowed such pre-1976 devices to remain on the market at least temporarily following adoption of the MDA. *Id.*

medical devices reach the market via PMA review and approval. *Id.* at 13a. The court said that the § 510(k) process "differs dramatically from the PMA process." *Id.* The court explained that while the latter involves an intense FDA review of the device and results in PMA "approval" of the specific device design only if FDA determines that that design provides "reasonable assurance" of safety and effectiveness, the § 510(k) process "'does not in any way denote FDA approval of the device,'" but rather simply signifies that the device is *as safe and effective* as grandfathered medical devices (which were never themselves reviewed for safety and effectiveness. *Id.* at 13a-14a (quoting 21 C.F.R. § 807.97).

The appeals court concluded that the "dramatic[]" difference in the two market-entry methods made a decisive difference under the MDA's express preemption provision, § 360k(a).[4] The court determined that because FDA intensely reviews and actually approves the design and labeling of PMA devices, FDA's approval of the specific design and labeling of the Evergreen Balloon Catheter qualified as a "requirement applicable under this Act to the device," within the meaning of § 360k(a)(1). *Id.* at 25a-29a. The court also concluded that "the Riegels' claims would, if successful, result in state 'requirements' [within the meaning of § 360k(a)] that differed

---

[4] Section 360k(a) provides in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> > (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

from or added to [the] standards" specified in Medtronic's approved PMA application. *Id.* at 30a.

In finding that the Riegels' design and labeling claims were expressly preempted by § 360k(a), the appeals court deemed the claims to present a direct conflict with the federal PMA approval scheme:

> Yet the Riegels' claims would premise liability on Medtronic's failure to have done something with the Evergreen Balloon Cath[et]er other than adhere to the PMA-approved standards. [¶] In fact, it is unclear what a manufacturer of a PMA-approved device would do when faced with a jury verdict on a plaintiff's common law claims, given that the manufacturer would nonetheless be unable to make any modifications affecting the device's safety and effectiveness without obtaining further FDA approval. Moreover, it is certainly conceivable that different juries would reach conflicting verdicts about the same medical devices, thus rendering it almost impossible for a device to comply simultaneously with its federal PMA (which, after all, can only change after an extensive process) and with the various verdicts issued by different juries around the country.

Id. 33a-34a.

The appeals court agreed with the district court that the Riegels' negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's surgery had not been manufactured in accordance with the PMA-approved standards. The court explained, "A jury verdict in the Riegels' favor would not have imposed state requirements that differed from, or added to, the PMA-

approved standards for this device, but would instead have simply sought recovery for Medtronic's alleged deviation from those standards." *Id.* 35a-36. The court went on to uphold the district court's grant of summary judgment to Medtronic on the negligent manufacturing claim, finding that the Riegels had submitted no competent evidence to challenge Medtronic's explanation regarding why the catheter had burst. *Id.* 38a-43a.[5]

In dissent, Judge Pooler would have held that Congress, in adopting § 360k(a), did not intend to include common law tort actions within the category of state "requirement[s]" subject to preemption. *Id.* at 45a-54a.

SUMMARY OF ARGUMENT

WLF fully agrees with Medtronic's contention that Congress intended to preempt the state-law tort actions at issue in this case. That intent is apparent from the language of the MDA's express preemption provision, 21 U.S.C. § 360k(a). But that intent can *also* be inferred from the overall structure of the MDA; that structure establishes a federal system for determining when new, Class III medical devices are sufficiently safe and effective to be marketed on a nationwide basis in accordance with an FDA-mandated design and labeling. The Riegels' causes of action conflict with that system by asking state courts to determine that the FDA-mandated design and labeling are deficient.

Medtronic has explained at length why § 360k(a) demonstrates Congress's intent to preempt the Riegels' causes of action. WLF will not repeat all of those arguments here.

---

[5] Petitioner did not seek review of that portion of the appeals court's ruling, and thus issues related to negligent manufacturing are not now before the Court.

Rather, we wish to emphasize three points regarding that statutory provision. First, Petitioner's assertion that § 360k(a) was never intended to apply to common law actions not only is inconsistent with the views of five of the nine Justices in *Lohr*, but also is inconsistent with other decisions of this Court that have interpreted similarly worded express preemption provisions as applying to common law causes of action. *See Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). Second, § 360k(a) applies broadly to "any" requirement that is imposed by a State and meets the other criteria established by the statute. Accordingly, there is no statutory basis for Petitioner's assertion that those common law duties that can be said to apply generally to all product manufacturers rather than focusing on specific medical devices are not state "requirement[s]" subject to § 360k(a) preemption. Third, the appeals court decision does not, as Petitioner argues, deprive patients of a remedy for injuries caused by defective medical devices. When it approves a PMA application for a medical device, FDA thereby determines that a medical device designed, manufactured, and labeled in accordance with the FDA-mandated specifications *is not defective*. Thus, by limiting a patient's litigation options, all the MDA is doing is preventing the patient from suing the manufacturer of a non-defective device. Until such time as FDA reverses a decision approving a device's design and labeling, § 360k(a) prohibits States from arriving at a contrary decision by applying a different set of requirements to the device.

In addition to the express preemption arguments articulated by Medtronic, the appeals court decision can be sustained based on an implied preemption argument. Implied preemption is fairly encompassed within the Question Presented, which focuses on whether Congress intended to preempt Petitioner's causes of action. Once the preemption *claim* has been raised, the parties and the Court are free to

address any *arguments* relevant to that issue, regardless whether those specific arguments were raised or passed on in the courts below.

Among the circumstances under which Congress is deemed to have impliedly preempted state law is when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. The Riegels' causes of action are preempted for precisely that reason: recovery under those causes of action would undermine the PMA process established by Congress, by second-guessing FDA determinations that approved products are not defective when marketed in accordance with the FDA-approved labeling and design specifications.

In *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court held that federal law preempted state-law claims that a medical device manufacturer made fraudulent misrepresentations to FDA for the purpose of obtaining FDA approval for its device. The Court unanimously held that Congress had impliedly intended to preempt such fraud-on-the-FDA claims when it adopted the MDA and the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, because adjudication of such claims would conflict with the FDA product-approval process. *Buckman*, 531 U.S. at 348. Similarly, permitting the Riegels and other injured plaintiffs to bring state-law suits alleging that a PMA medical device is defectively designed or improperly labeled would undermine FDA requirements mandating that the device be designed and labeled in that precise manner.

Such suits cannot be defended based on an argument that federal design and labeling requirements serve merely as a floor and that states are permitted to impose more exacting safety requirements. FDA specifies precise design specifications for a medical device based on a detailed

assessment that the prescribed design is safe and effective. Congress cannot have intended to permit a state-court jury to second-guess such design decisions, where the practical effect would be to require a manufacturer to adopt a different design – one that FDA might well decide is neither safe nor effective. Similarly, FDA imposes labeling requirements based on its considered determination regarding the proper mix of contraindications and warnings. FDA regularly directs manufacturers to limit the strength of warnings included on a label, to avoid scaring away consumers who would benefit from using the product. Yet, if Petitioner were to prevail on her failure-to-warn claim, New York would in effect be requiring Medtronic to alter the labeling mandated by FDA. Under such circumstances, Congress is deemed to have impliedly preempted such common law suits.

The fact that the MDA includes an express preemption provision does not preclude a finding of implied preemption. The Court has on several occasions held that a common law cause of action is impliedly preempted by federal law even though the federal statute at issue contained an express preemption provision. Indeed, although the *Lohr* plurality was skeptical that § 360k(a) should ever operate to preempt a common law cause of action, those same four Justices were more receptive to the idea that the MDA might impliedly preempt some common law causes of action based on conflict preemption. *Lohr*, 518 U.S. at 503 (plurality opinion).

ARGUMENT

I. PETITIONERS' DESIGN DEFECT AND FAILURE-TO-WARN CLAIMS ARE PREEMPTED BY § 360k(a)

Section 360k(a) contains four principal elements. To establish preemption under § 360k(a), one must demonstrate:

- a state "requirement";
- a federal "requirement applicable . . . to the device" under the FDCA;
- that the state "requirement" is "different from, or in addition to" the federal "requirement applicable . . . to the device" under the FDCA; and
- that the state "requirement" "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" under the FDCA.

Medtronic has explained at length in its brief why the Second Circuit was correct in concluding that Medtronic had met each of those four elements. WLF fully concurs in those arguments and will not repeat them here. Rather, we wish to focus on three points that help to explain why the Riegels' common law causes of action do, in fact, constitute state "requirements" within the meaning of § 360k(a).

A. The Language of § 360k(a) Has Been Interpreted in Lohr and Other Cases As Evidence of a Congressional Intent to Preempt Common Law Causes of Action

Petitioners assert that § 360k(a) was never intended by Congress to apply to common law causes of action. That assertion flies in the face of several decisions of this Court in which the Court stated that both § 360k(a) and similarly worded express preemption statutes did, indeed, apply to common law causes of action.

Although *Lohr* ultimately determined that the common law causes of action at issue in that case were not preempted,

five of the nine Justices stated that such causes of action against medical device manufacturers can and often do constitute state "requirement[s]" within the meaning § 360k(a). *See Lohr*, 518 U.S. at 511-14 (O'Connor, J., concurring in part and dissenting in part) (joined by Chief Justice Rehnquist and Justices Scalia, and Thomas); *id.* at 504 (Breyer, J., concurring in part and concurring in the judgment) ("One can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law."). Justice Breyer drew support for that conclusion from the Court's previous decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), stating that *Cipollone* "made clear that similar language [*i.e.*, preemptive language similar to that contained in § 360k(a)] 'easily' encompassed tort actions because '[state] regulation can be as effectively asserted through an award of damages as through some form of preventive relief.'" *Lohr*, 518 U.S. at 504 (quoting *Cipollone*, 505 U.S. at 521). Similarly, in *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), the Court held that 7 U.S.C. § 136y(b) – the express preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a provision that includes "any requirement" language similar to the language in § 360k(a) – operated to preempt common law causes of action.[6]

Petitioner's efforts to rewrite *Bates* are without merit. Asserting that a common law court judgment cannot constitute a state "requirement" within the meaning of § 360k(a), she cites *Bates* for the proposition that "'an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.'" Pet. Br. 12 (quoting *Bates*, 544 U.S. at 445). When read in context, the quoted language from *Bates* strongly

---

[6] Section 136y(b) provides that States "shall not impose or continue in effect any requirement for labeling or packaging in addition to or different from those required under this subchapter."

supports Medtronic. The quoted language appears in a section of the opinion that discusses when a common law judgment should be deemed a preempted "requirement" for labeling or packaging within the meaning of FIFRA. The lower court had ruled that the FIFRA preemption provision operates to preempt common law causes of action *whenever* a finding of liability on those claims would "induce" a manufacturer to alter its product label. The Court rejected that approach, stating, "This effects-based test finds no support in the text of [the FIFRA preemption provision], which speaks only of 'requirements.'" *Id.* Rather, the Court explained:

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common law duty at issue.

Id. (citing *Cipollone,* 505 U.S. at 524). The Court said that a design defect claim should not be deemed a "requirement" regarding "labeling or packaging" merely because, if successful, it would "induce a manufacturer to alter its label to reflect a change in the list of ingredients or a change in the instructions for use necessitated by the improvement in the product's design." *Id.* at 445-46. Under the examine-the-elements-of-the-duty approach endorsed by *Bates*, the Court determined that the petitioners' fraud and negligent-failure-to-warn claims were premised on common law rules that *did* qualify as "requirements for labeling or packaging" because they "set a standard for a product's labeling that the [defendant's] label [wa]s alleged to have violated by containing false statements and inadequate warnings. *Id.* at 446.

Similarly, the Riegels' causes of action, if successful, unquestionably would constitute "requirement[s]" within the

meaning of § 360k(a). A design defect and failure-to-warn judgment in Petitioner's favor would require Medtronic to alter the FDA-mandated design and labeling of its product.

B. Section § 360k(a) Does Not Exclude State Rules of General Applicability from Being Classified as "Requirement[s]"

Section 360k(a) broadly preempts "any" state requirement that meets the other criteria established for preemption. Petitioner nonetheless insists that state rules of general applicability – a category that includes virtually all common law tort rules – do not fall within § 360k(a)'s definition of a state "requirement" and thus are never subject to preemption. Pet. Br. 34-39.

WLF notes initially that that approach was rejected by five Justices in *Lohr*; they determined that a significant number of common law tort actions were preempted by § 360k(a), notwithstanding that all such actions are premised on broadly applicable tort principles. Moreover, nothing in the statute supports Petitioner's constricted definition of a state "requirement." Section 360k(a) refers to preemption of "any" applicable requirement. Moreover, even when a tort judgment is based on generally applicable common law rules, it has the effect of imposing on the defendant a product-specific common law duty that does not leave it free to continue marketing its product in the same way as it has in the past. As *Bates* explained, where (as here) any judgment would be premised on common law rules that would dictate future marketing decisions, such rules are "requirements" within the meaning of federal preemption statutes. *Id.* at 446.

C. States Undermine the Objectives of the MDA When They Second-Guess an FDA Decision to Approve Marketing of Life-Saving Medical Devices Pursuant to FDA-Mandated Design and Labeling Requirements

Petitioner asserts that the Second Circuit's preemption rule will foreclose remedies for many people injured by defective PMA devices. Pet. Br. 43-46. That assertion is without merit.

When it approves a PMA application for a medical device, FDA thereby determines that a medical device designed, manufactured, and labeled in accordance with the FDA-mandated specifications *is not defective*. Thus, by limiting a patient's litigation options, all § 360k(a) is doing is preventing the patient from suing the manufacturer of a non-defective device. FDA continues to monitor medical devices after it has approved a PMA application and marketing of the devices has begun. If it subsequently determines that a device is defective, it has the authority *inter alia* to withdraw approval, 21 U.S.C. § 360e(e), and to recall devices already in the marketplace. 21 U.S.C. § 360h(e). But until such time as FDA takes action to reverse a decision approving the marketing of a device with FDA-mandated design specifications and labeling, § 360k(a) prohibits States from arriving at a contrary decision by applying a different set of requirements to the device.

Moreover, § 360k(a) does not leave injured patients without remedies. For example, as the Second Circuit held, they are still free to pursue other remedies against the manufacturer, including negligent manufacture and breach of express warranty. Alternatively, they can pursue remedies against others who may be responsible for the injuries, such as their physicians. But Congress recognized that no medical

product is without risk and that use of Class III medical devices often results in injuries for which no one can be deemed blameworthy. Under those circumstances, Congress acted reasonably in limiting the liability of manufacturers who, like Medtronic in this case, have marketed their medical devices in conformance with all applicable FDA requirements and after FDA has determined that their devices are safe and effective.

The MDA was intended to strike a balance between the need to protect the public from unsafe and ineffective medical devices and the danger that unnecessary restrictions would deter innovations in medical device technology. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 9 (1976), *reprinted in* Daniel F. O'Keefe, Jr. & Robert A. Spiegel, *An Analytical Legislative History of the Medical Device Amendments of 1976*, App. III (1976). Section 360k(a) addresses the latter concern by ensuring that excessive tort liability does not deter medical innovation. It also addresses Congress's concern that, "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." *Id.* at 45. *See also* Pet. App. at 33a-34a ("It is certainly conceivable that different juries would reach conflicting verdicts about the same medical devices, thus rendering it almost impossible for a device to comply simultaneously with its federal PMA (which, after all, can only change after an extensive process) and with the various verdicts issued by different juries around the country.").

II. PETITIONERS' DESIGN DEFECT AND FAILURE-TO-WARN CLAIMS ARE IMPLIEDLY PREEMPTED BY THE MDA

The issue before the Court is whether Congress intended to preempt common law actions of the sort being pressed by

Petitioner. The Second Circuit relied on the express preemption provisions of § 360k(a) to answer that question in the affirmative. WLF agrees with the appeals court's analysis. In addition, WLF submits that the answer would be the same if this Court were to employ an implied preemption analysis. Accordingly, the appeals court decision can be sustained on either basis.

A. Implied Preemption Is Fairly Encompassed Within the Question Presented

The Court granted review to consider whether, as found by the Second Circuit, Congress intended to preempt common law design defect and failure-to-warn claims filed against the manufacturer of a PMA medical device. Accordingly, implied preemption is fairly encompassed within that question; the ultimate issue (congressional intent) is the same whether it is determined on the basis of express statutory language or is inferred on the basis of the structure of the MDA.[7] Once review is granted to consider an issue, the Court has never limited the parties to the specific arguments on that issue that were raised or considered below. *See Lebron v. Nat'l Railroad Passenger Corp.*, 513 U.S. 374, 379 (1995) ("Our traditional rule is that 'once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they raised below.'") (quoting *Yee v. Escondido*, 503 U.S. 519, 534 (1992).

---

[7] *See Lohr*, 518 U.S. at 485 ("'[T]he purpose of Congress is the ultimate touchstone' in every preemption case.") (quoting *Cipollone*, 505 U.S. at 516).

B. The Court Has Regularly Inferred Congressional Intent to Preempt State Laws That Conflict with Federal Law

When express statutory language does not directly answer whether and to what extent Congress intended to preempt state law, "courts must consider whether the federal statute's 'structure and purpose,' or nonspecific statutory language, nonetheless reveal a clear, but implicit, preemptive intent." *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30 (1996) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). Findings of such "clear, but implicit, preemptive intent" have generally been grouped into two categories: (1) field preemption; and (2) conflict preemption. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995).

Field preemption is said to occur:

> [I]f a scheme of federal regulation is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," if "the Act of Congress . . . touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject," or if the goals "sought to be obtained" and the "obligations imposed" reveal a purpose to preclude state authority. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

Wisconsin Public Intervenor v. Mortier, 501 U.S. 597, 605 (1991).

Conflict preemption is said to occur:

> [T]o the extent that state and federal law actually conflict. Such a conflict arises when "compliance with

> both federal and state regulation is a physical impossibility," *Florida Lime and Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 142-143 (1963), or when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz,* 312 U.S. 52 (1941).

Wisconsin Public Intervenor, 501 U.S. at 605.

C. Recovery Under the Riegels' Causes of Action Is Preempted Because It Would Undermine the PMA Process Established by Congress

WLF submits that the Riegels' causes of action are impliedly preempted because they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Recovery under those causes of action would undermine the PMA process established by Congress, by second-guessing FDA determinations that approved products are not defective when marketed in accordance with the FDA-approved labeling and design specifications.

In *Buckman*, the Court held that federal law preempted state-law claims that a medical device manufacturer made fraudulent misrepresentations to FDA for the purpose of obtaining FDA approval for its device. *Buckman*, 531 U.S. at 348. The Court unanimously held that Congress had impliedly intended to preempt such fraud-on-the-FDA claims when it adopted the MDA and the FDCA, because adjudication of such claims would conflict with the FDA product-approval process. *Id.* The Court explained:

> The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that this authority is used by the agency to achieve a somewhat delicate balance of

> statutory objectives. The balance sought by the Agency can be skewed by allowing fraud-on-the-FDA claims under state tort law.

Id.

Similarly, permitting the Riegels and other injured plaintiffs to bring state-law suits alleging that a PMA medical device is defectively designed or improperly labeled would undermine FDA requirements mandating that the device be designed and labeled in that precise manner. If state officials have reason to believe that PMA medical devices being marketed within their jurisdiction are defective, they can go to FDA to report their concerns and urge FDA to exercise its power to prevent further marketing of the drug. But allowing States to go forward independently with proceedings designed to determine whether the FDA-mandated product design is defective is an invitation to chaos.

Indeed, it was precisely such concerns about conflict between federal and state regulatory requirements that underlay the Second Circuit's express preemption finding. The appeals court explained its concern as follows:

> Yet the Riegels' claims would premise liability on Medtronic's failure to have done something with the Evergreen Balloon Cath[et]er other than adhere to the PMA-approved standards. [¶] In fact, it is unclear what a manufacturer of a PMA-approved device would do when faced with a jury verdict on a plaintiff's common law claims, given that the manufacturer would nonetheless be unable to make any modifications affecting the device's safety and effectiveness without obtaining further FDA approval. Moreover, it is certainly conceivable that different juries would reach conflicting verdicts about the same medical devices, thus

> rendering it almost impossible for a device to comply simultaneously with its federal PMA (which, after all, can only change after an extensive process) and with the various verdicts issued by different juries around the country.

Pet. App. 33a-34a. Such concerns could equally well have been cited as the basis for a conflict preemption determination.

Of course, Congress is free to disclaim an interest in preempting state law, even state law that (as here) conflicts with a federal regulatory regime by standing as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. But Petitioner has pointed to nothing in the MDA suggesting such a congressional intent. This Court has held that, in the absence of affirmative statutory evidence that Congress did not want to preempt conflicting state law, normal conflict preemption principles are applicable. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873-74 (2000) ("no airbag" tort suits against auto manufacturers held impliedly preempted by federal auto safety rules, in absence of evidence that express preemption clause and savings clause in National Traffic and Motor Safety Act of 1966, 15 U.S.C. § 1381 *et seq.*, were intended to supplant conflict preemption analysis).

Riegels' causes of action cannot be defended based on an argument that federal design and labeling requirements serve merely as a floor and that states are permitted to impose more exacting safety requirements. FDA specifies precise design specifications for a medical device based on a detailed assessment that the prescribed design is safe and effective. *See, e.g.* 21 C.F.R. §§ 814.20, 814.44, 814.80. Congress cannot have intended to permit a state-court jury to second-guess such design decisions, where the practical effect would

be to require a manufacturer to adopt a different design – one that FDA might well decide is neither safe nor effective.

Similarly, FDA imposes labeling requirements based on its considered determination regarding the proper mix of contraindications and warnings. FDA regularly directs manufacturers to limit the strength of warnings included on a label, to avoid scaring away consumers who would benefit from using the product. Yet, if Petitioner were to prevail on her failure-to-warn claim, New York would in effect be requiring Medtronic to alter the labeling mandated by FDA. Under such circumstances, Congress is deemed to have impliedly preempted such common law suits.

Indeed, based on concerns that overwarning on product labels (brought about in reaction to common law failure-to-warn suits) could cause adverse health effects, FDA has adopted the position that failure-to-warn claims against drug manufacturers are impliedly preempted in a broad range of circumstances. FDA, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) ("Overwarning, just like underwarning, can . . . have a negative effect on patient safety and public health.").

Perhaps the most well-known recent example of overwarning involves depression drugs. Beginning in 2004, FDA began focusing on reports that adolescent patients taking drugs in the selective serotonin reuptake inhibitor (SSRI) class were having suicidal thoughts shortly after beginning drug therapy. After consulting with advisory committees regarding the appropriate risk management strategy in response to these reports, FDA decided to seek labeling revisions for all SSRIs. On March 22, 2004, FDA issued a Public Health Advisory recommending that labeling be modified to reflect potential suicide risks. FDA noted in the Advisory that it had "not

concluded that [SSRI side effects] are a precursor to either worsening of depression or the emergence of suicidal impulses," but it still recommended the change to alleviate "concern." Public Health Advisory, FDA, Worsening Depression and Suicidality in Patients Being Treated With Antidepressant (Mar. 22, 2004), *available at* http://www.fda.gov/cder/drug/antidepressants/AntidepressanstPHA.htm.

Shortly after the labeling change, the psychiatric community, patients, and caregivers began expressing concern about undertreatment of depression and a sudden spike in suicidal behavior. Pediatric antidepressant prescriptions had fallen by about 50 percent between 2003 and 2005, according to a study published in June 2007 in *The American Journal of Psychiatry*. Anne M. Libby, Ph.D. et al., *Decline in Treatment of Pediatric Depression After FDA Advisory on Risk of Suicidality With SSRIs*, 164 Am. J. Psychiatry 884, 887 (2007). A September 2007 study in that journal reported that, as pediatric antidepressant prescriptions fell in 2003-2004, the adolescent suicide rate rose by 14 percent.[8] The authors of the study reasoned that "the public health warnings may have left some of the most vulnerable youths untreated." Robert D. Gibbons, Ph.D. et al., *Early Evidence on the Effects of Regulators' Suicidality Warnings on SSRI Prescriptions and Suicide in Children and Adolescents*, 164 Am. J. Psychiatry 1356, 1358-1359 (2007).

The same concerns regarding overwarning apply to medical devices. If, in response to common law failure-to-warn suits, device manufacturers are required to add warnings

---

[8] Data available from the Centers for Disease Control and Prevention on U.S. suicide rates was only available at the time of the study through 2004.

to their product labels – warnings that are in excess of those deemed appropriate by FDA – one can expect a certain number of patients to abstain inappropriately from use of medically indicated device. Congress did not intend to permit state juries to second-guess FDA's considered judgment regarding which warnings should be placed on the label of a medical device.

D. The Existence of an Express Preemption Provision in the MDA Does Not Preclude an Implied Preemption Finding

The fact that the MDA includes an express preemption provision does not preclude a finding of implied preemption. The Court has on several occasions held that a common law cause of action is impliedly preempted by federal law even though the federal statute at issue contained an express preemption provision. For example, in *Geier*, the Court held that "no airbag" common law suits are implied preempted by federal highway safety law, after finding that the express preemption provision of the National Traffic and Motor Safety Act of 1966 did *not* preempt such suits. *Geier*, 529 U.S. at 869 (existence of express preemption provision "does not foreclose (through negative implication) any possibility of implied conflict preemption). In *Buckman*, the Court determined that fraud-on-the-FDA lawsuits are impliedly preempted (under conflict preemption analysis) by the MDA and the FDCA and thus deemed it unnecessary to determine whether § 360k(a) also preempted such lawsuits. *Buckman*, 531 U.S. at 348 n.2.

Indeed, the *Lohr* plurality, while generally looking askance at express preemption (under § 360k(a)) of common law suits against manufacturers of § 510(k) medical devices, explicitly held open the possibility of implied conflict preemption in a proper suit. *Lohr*, 518 U.S. at 503 (plurality opinion). Moreover, Justice Breyer's concurring opinion, while nominally focusing on whether § 360k(a) preempts

common law causes of actions against device manufacturers, makes clear his view that the strongest arguments supporting preemption are ones demonstrating that a state common law rule is interfering with FDA regulation of medical devices. *Lohr,* 518 U.S.. at 503-508 (Breyer, J., concurring in part and concurring in the judgment).

CONCLUSION

The Washington Legal Foundation respectfully requests that the Court affirm the judgment of the appeals court.

Respectfully submitted,

Daniel J. Popeo
Richard A. Samp
(Counsel of Record)
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

Dated: October 19, 2007